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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,825	01/11/2002	Anne R. Kopf-Sill	100/10010	8044

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CALIPER LIFE SCIENCES, INC.
605 FAIRCHILD DRIVE
MOUNTAIN VIEW, CA 94043-2234

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,825	KOPF-SILL ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Parce et al., 5,942,443.

As to claim 1, Parce et al. teaches a method of flowing fluid in a non-sipper microfluidic device to emulate a fluid flow profile in a microfluidic device comprising an external capillary, the method comprising:

flowing a sample from a first internal source (fig. 1, reference 104, for example) into a non-sipper main channel (110) via a capillary emulator channel, wherein the non-sipper capillary emulator channel simulates the external capillary (col. 9, lines 27-32, lines 37-38, and lines 56-58, wherein Parce teaches that the introduction of individual, discrete volumes of test compounds may be carried out by a number of methods, including use of micropipettors or electropipettors utilizing electroosmotic fluid direction, or alternatively through internal reservoirs via separate channels fluidly connected to the sample channel 112. To "emulate" according to Applicant's definition on page 8, second paragraph, of the specification means to imitate, equal, simulate, copy, etc. flow

characteristic(s) of a sipper device, e.g., hydrodynamic resistance, flow rate, amount of fluid flow or the like. Parce teaches emulating--i.e., to imitate, equal, simulate, or copy, etc.--the flow characteristics, such as introducing a discrete amount of fluid flow, of a micropipettor by teaching that a non-sipper channel can be alternatively used to introduce a discrete volume of test compound);

flowing the sample through the non-sipper main channel (col. 9, lines 56-63); and

flowing one or more reagents from a second internal source (106) into the non-sipper main channel via a non-sipper side channel (114).

As to claim 2, the non-sipper microfluidic device comprises a planar microfluidic device (see fig. 1.)

As to claim 3, the external source comprises a microwell plate (col. 20, line 61.)

As to claim 4, flowing fluid through the non-sipper microfluidic device comprises creating one or more sample plug (i.e., test compounds, col. 9, lines 60-61) and one or more buffer plug in the non-sipper microfluidic device (i.e., spacer buffer, col. 9, lines 60-61 and 65), which one or more sample plug and one or more buffer plug emulate fluid flow from the external source into the microfluidic device via the external capillary.

As to claim 5, creating the sample plug(s) and the buffer plug(s) comprises:

(i) loading a sample from a first source (i.e., one of the separate reservoirs containing test compounds, in col. 9, line 57) into a channel (112, col. 9, line 56) of the non-sipper microfluidic device,

(ii) loading a buffer from a second source (i.e., one of the separate reservoirs containing spacer buffer compound, in col. 9, lines 57-59, and line 65) into the channel;

(iii) applying pressure to the sample in the channel, thereby creating the sample plug(s) and transporting the sample plug(s) through the channel (i.e., through fluid direction scheme, col. 9, lines 60-63 and col. 3, lines 22-31); and,

(iv) applying pressure to the buffer in the channel, thereby creating the buffer plug(s) and transporting the buffer plug(s) through the channel (i.e., through fluid direction scheme, col. 9, lines 60-63 and col. 3, lines 22-31.)

As to claim 6, the method further comprises alternately performing step (i) and step (ii) (see col. 9, lines 38-39 and lines 63-64).

As to claim 7, the method further comprises repeating steps (i) and (ii) (col. 9, lines 38-39 and lines 63-64.)

As to claim 8, the method further comprises continuously performing step (iii) and step (iv) (col. 9, ines 38-39 and lines 63-64.)

As to claim 9, the method further comprises alternately performing step (i) and step (ii) while simultaneously performing step (iii) and step (iv) (col. 9, lines 38-39 and lines 63-64.)

As to claim 11, the first source and the second source comprise internal reservoirs (col. 9, line 57.)

As to claim 12, the method further comprises loading the sample from the first source into the channel of the non-sipper microfluidic device by applying a first electrokinetic gradient between the first source and a waste reservoir (col. 13, line 35) and loading the buffer from the second source into the channel by applying a second

electrokinetic gradient between the second source and the waste reservoir (col. 13, lines 32-40, and col. 9, lines 38-39, and lines 63-64, and col. 3, lines 22-32.)

As to claim 13, the waste reservoir comprises an internal reservoir (col. 13, lines 32-40).

As to claim 14, the method further comprises alternately applying the first electrokinetic gradient and the second electrokinetic gradient (col. 9, lines 38-39, and lines 63-64.)

As to claim 15, the method further comprises alternately applying the first electrokinetic gradient ad the second electrokinetic gradient and simultaneously applying pressure to the sample in the channel and to the buffer in the channel (col. 9, lines 38-39 and lines 63-64.)

As to claim 16, the method further comprises loading the sample from the first source into the channel by applying pressure to the sample and loading the buffer from the second source into the channel by applying pressure to the buffer (col. 9, lines 38-39, and lines 63-64.)

As to claim 17, the method further comprises alternately applying pressure to the sample and to the buffer (col. 9, lines 38-39 and lines 63-64.)

As to claim 18, the method further comprises alternately applying pressure to the sample in the first source and to the buffer in the second source (col. 9, lines 38-39 and lines 63-64) and concurrently applying pressure to the sample in the channel and to the buffer in the channel (col. 13, lines 32-40.)

As to claim 19, flowing fluid through the non-sipper microfluidic device comprises

(i) flowing a sample from a first internal source (i.e., a reservoir containing test compound, col. 9, lines 57-59) into a non-sipper main channel via a capillary emulator channel (112, col. 9, line 56);

(ii) flowing the sample through the non-sipper main channel (col. 9, lines 60-63); and

(iii) flowing one or more reagent from at least a second internal source (i.e., a reservoir containing spacer buffer, col. 9, lines 57-59, and line 65) into the non-sipper main channel via a non-sipper side channel (i.e., separate channel, col. 9, line 58.)

As to claim 20, the capillary emulator channel simulates the external capillary (col. 9, lines 56-58).

As to claim 21, the non-sipper main channel simulates a sipper main channel (col. 9, lines 56-58).

As to claim 22, the non-sipper side channel simulates a sipper side channel (col. 9, lines 56-58.)

As to claim 23, simulates comprises having substantially the same hydrodynamic resistance as an equivalent channel in the microfluidic device comprising the external capillary (col. 9, lines 56-58; see also Examiner's comments above regarding "emulate" and "simulate".)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al., 5,942,443.

Parce et al. discloses the invention substantially as claimed (see above).

However, as to claim 10, Parce et al. does not disclose that step (iii) and step (iv) further comprises simultaneously applying a first pressure to the sample and a second pressure to the buffer, wherein the first pressure and the second pressure are different. Parce et al. however does teach that fluid movement depends on various factors including solvent viscosity and electric field strength (col. 12, lines 58-67), and that there may be multiple, independent voltage sources and a voltage controller that is electrically connected to each reservoir (col. 13, lines 3-12.) Parce et al. also teaches that modulation of the voltages applied at the various reservoirs can move and direct fluid flow through the interconnected channel structure in a controlled manner to effect the fluid flow for the desired screening assay and apparatus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a pressure to the sample that is different from the pressure applied to the buffer because Parce et al. teaches that applied pressure on fluids can be

changed to account for factors such as solvent viscosity and as would be necessary to move and direct fluid flow in a controlled manner to effect the fluid flow for the desired screening assay.

Also, as to claim 24, Parce et al. does not teach that simulates comprises having substantially the same length, width, and depth as an equivalent channel in the microfluidic device comprising the external capillary. Parce et al. does teach however that the dimensions of a channel may be varied to adjust for incubation time (col. 15, lines 21-25) or to adjust for resistance within the channel (col. 20, lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide in the non-sipper microfluidic device a channel having the same length, width, and depth as an equivalent channel in a microfluidic device comprising external capillary because this dimension is an optimum or workable range and it has been held that where the general conditions of a claim are disclosed in the prior art, as is in the case at hand, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Also, as to claim 25, Parce et al. does not disclose that simulates comprises flowing substantially the same amount of the reagent or the sample as an equivalent channel in the microfluidic device comprising the external capillary. Parce et al. however does teach that movement of test compounds can be controlled (col. 3, lines 22-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to flow substantially the same amount of the reagent or the sample as an equivalent channel in the microfluidic device comprising the external capillary

because this amount is an optimum or workable range and it has been held that where the general conditions of a claim are disclosed in the prior art, as is in the case at hand, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed July 1, 2005 have been fully considered but they are not persuasive.

Applicant argues that Parce's teaching of a second microfluidic device that is an anlternative to a first microfluidic device does not teach either explicitly or impliedly that the second device emulates (i.e., imitates, equals, simulates, or copies) the first device.

Applicant agues that the word "alternative" is define in the dictionary to mean 'offering or expressing a choice" and that the alternatives described by Parce are not intended to imitate, equal, simulate, or copy, but are simply available choices, whose appeal may depend entirely on the circumstances of the individual making the choice. The Office does not find this persuasive. Examiner notes that "emulate" according to Applicant's definition on page 8, second paragraph, of the specification means to imitate, equal, simulate, copy, etc. flow characteristic(s) of a sipper device, e.g., hydrodynamic resistance, flow rate, amount of fluid flow or the like. Parce teaches that the introduction of individual, discrete volumes of test compounds can be carried out by using separate (internal) reservoirs connected to a sample channel, and using

appropriate fluid direction schemes, as an alternative to using a micropipettor to introduce test compounds (from an external source) into the device (col. 9, lines 27-32, and lines 56-63.) Although Parce does not use the word emulate, imitate, equal or simulate, Parce nevertheless teaches that the introduction of *a discrete volume* of test compound can be alternatively achieved through the two disclosed methods. Parce thus teaches one to imitate, equal, simulate, or copy the flow characteristics--for example, providing a discrete volume of test compound—of a sipper device (i.e., micropipettor) through use of a non-sipper channel.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/18/06